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Docket No: D-2804CON2

REMARKS

Applicants are in receipt of the Office Action mailed July 5, 2005, and have the following comments.

Interview Summary

Applicants thank the Examiner for the telephonic interview conducted July 14, 2005, in which Ms. Janet McGhee of the undersigned's office spoke with the Examiner to ask whether the Office Action contained a typographical error, applying a rejection pursuant to 35 USC § 102(b) over Loftsson et al., U.S. Pat. No. 5481,954. The Examiner clarified that the rejection was instead over Loftsson et al., U.S. Patent. No. 5472,954. Applicants are grateful for the Examiner's courtesy during this interview.

Objection to claim 32

The Examiner has objected to claim 32 because of the misspelling of the word "prednisolone". Applicants regret any inconvenience this error may have caused, and have amended claim 32 to correct this misspelled word.

Rejection over 35 USC §112(2)

The Examiner has rejected claims 32 and 42 as being allegedly indefinite in the use of the term "apparent solubility" in claim 32, and its effect of dependant claim 42. Applicants have deleted the word "apparent" from claim 32, and thus now believe this rejection is moot. This clarifying amendment does not narrow the scope of either claim, and

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thus is not subject to the rule of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 62 USPQ2d 1705 (S.Ct. 2002).

Rejection pursuant to 35 USC §102(b)

The Examiner has rejected claims 31-36, 39-46 and 49-50 as allegedly anticipated over Loftsson et al., U.S. Patent. No. 5472,954. Applicants respectfully traverse this rejection for the following reasons.

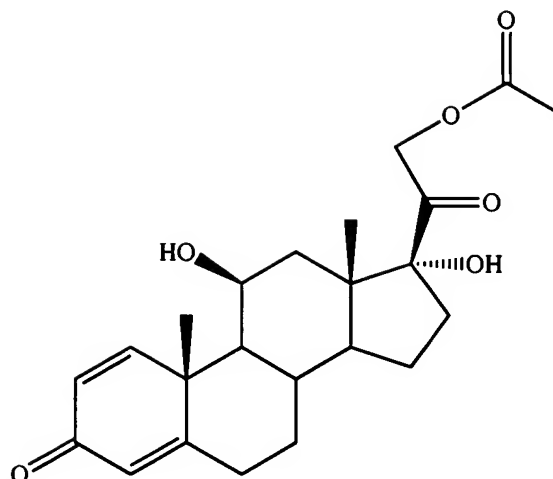
A claim is not anticipated unless a single prior art reference contains each and every limitation of the claim and teaches a person of skill in the art to make and use the invention without undue experimentation. See e.g., *In re Paulsen*, 31 USPQ 2d 1671 (Fed. Cir 1994).

Claim 31, upon which all other pending claims depend, is drawn to an ophthalmic aqueous composition comprising a therapeutically effective amount of prednisolone acetate and a cyclodextrin derivative in solution.

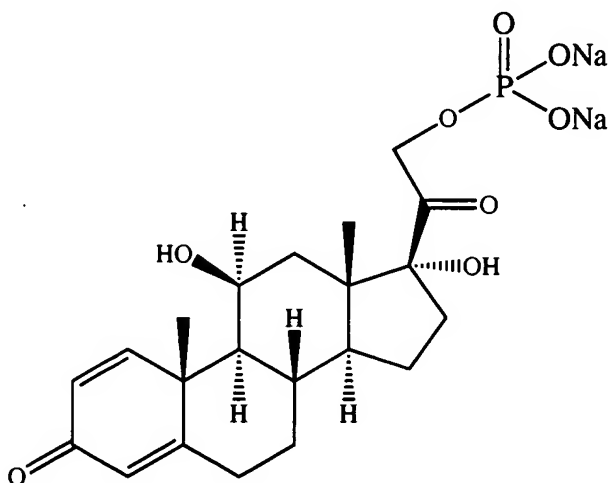
The Examiner has alleged that Loftsson et al. anticipates the pending claims because it teaches an ophthalmic composition comprising "prednisolone". (Office Action of July 5, 2005, page 4.) However, the present claims are drawn to a composition comprising prednisolone acetate.

According to a Pfizer document (a copy of which is provided with this communication) prednisolone acetate has the following structure:

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By contrast, NDA 19-157/S-018 (a copy of which is also provided with this communication) describes the structure of prednisolone sodium phosphate:



Moreover, in the first paragraph of this latter document, reference is made to a third compound: "prednisolone base".

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The present claims 31-50 are clearly drawn to compositions comprising a particular chemical entity, prednisolone acetate, having chemical, physical, and biological properties specific to this compound. By contrast, Loftsson refers in table 10, column 28 merely to "prednisolone".

Loftsson does not refer to prednisolone acetate, nor can a simple reference to "prednisolone" be read to unambiguously and inherently refer to prednisolone acetate.

In light of these facts, Applicants maintain that Loftsson does not disclose the limitations of claim 31 and therefore of any of the pending claims dependant thereupon. As such, Loftsson does not anticipate claims 31-36, 39-46 and 49-50.

Rejection pursuant to 35 USC §103(a)

The Examiner has rejected claims 31, 36-38 and 46-48 as allegedly obvious over Loftsson, and claims 37-38 as allegedly obvious over Loftsson further in light of Dziabo et al., U.S. Patent No. 5,424,078. The Examiner alleges that Loftsson et al. teaches a preserved cyclodextrin and prednisolone ophthalmic composition, and that Dziabo et al. disclose chlorite as a preservative. Applicants respectfully traverse this rejection for the following reasons.

As discussed above, the Loftsson reference does not disclose an ophthalmic composition containing the compound being claimed in the present claims, prednisolone acetate. Rather, the Loftsson reference discusses a very large number of compounds (drugs, food additives, cosmetic additives and agrochemicals; see e.g., column 4, lines 1 and 2) which, Loftsson claims, may be formulated with a very large number of cyclodextrin derivatives and a very large number of selected polymers to enhance their solubility or decrease their water lability. A list of various cyclodextrins is disclosed in column 6; a large list of polymers is mentioned e.g., in column 7; a very large list of compounds to be

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complexed with the cyclodextrin and polymer is listed in columns 7-13. The compound prednisolone acetate is not mentioned anywhere in this reference.

The Manual of Patent Examining Procedure (MPEP), relying on long-established judicial precedent, states that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so in the references or otherwise within the knowledge of the person of ordinary skill in the art. See MPEP § 2143.01. There is nothing in Loftsson et al., or in the combination of Loftsson and Dziabo et al., that would suggest the specifically claimed compositions containing prednisolone acetate, a compound not even mentioned in either reference, or methods of using such compositions. For this reason, the Applicants respectfully request the Examiner to withdraw this rejection and permit the present claims to proceed to issue.

No fee is thought to be due in connection with this communication. However, if Applicants are in error in this regard, kindly use Deposit Account 01-0885 for the payment of any charge now due.

Respectfully submitted,



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